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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/340,196	06/28/1999	RYOJI KATO	990701	3596

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ARMSTRONG, KRATZ, QUINTOS, HANSON & BROOKS, LLP
1725 K STREET, NW
SUITE 1000
WASHINGTON, DC 20006

EXAMINER	
HOLLERAN, ANNE L	

ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 04/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/340,196	KATO ET AL.	
	Examiner	Art Unit	
	Anne L. Holleran	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/27/2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *59,68-75,77 and 78* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *59, 68-75 and 77 -78* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed 12/27/2005 is acknowledged. Claims 59, 68-75, 77 and 78 are pending and examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections Withdrawn:

3. The objection to claim 78 is withdrawn in view of the amendment changing the term "pectin" to "lectin.

4. The rejection of claims 59 and 68-78 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons of record is withdrawn in view of the amendment deleting the reference to use of "specific antibodies capable of binding to a specific structure of a sugar chain of a first type of thyroglobulin".

Claim Rejections Maintained and New Grounds of Rejection:

The rejection of claims 72 (see item #8 below) and 77 (see items #5-#8 below) is the new ground of rejection. The rejections of claim 72 and 77 were inadvertently left out of a previous rejection.

5. Claims 59, 68, 69, and 74 remain rejected under 35 U.S.C. 103(a) as being unpatentable over either Nakamura (U.S. Patent 5,571,729; issued 11/5/1996) or Satomura (U.S. Patent 5,780,247; issued 7/14/1998; effective filing 1/5/1991) in view of either Yamamoto (of record), Tarutani (of record), or Survilo (Survilo, L.I. et al., Vestsi Akademii Navuk Belarusi, Seryya Khimichnykh Navuk, 4: 103-107, 1997; abstract only). The rejection over Stanta is withdrawn. Upon further consideration, this rejection is applied to claim 77. **Therefore, claims 59, 68, 69, 74 and 77 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Nakamura (U.S. Patent 5,571,729; issued 11/5/1996) or Satomura (U.S. Patent 5,780,247; issued 7/14/1998; effective filing 1/5/1991) in view of either Yamamoto (of record), Tarutani (of record), or Survilo (Survilo, L.I. et al., Vestsi Akademii Navuk Belarusi, Seryya Khimichnykh Navuk, 4: 103-107, 1997; abstract only).**

6. Claims 70,71 and 78 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Katoh (U.S. Patent 5,591,589; issued 1/7/1997) in view of either Yamamoto (of record), Tarutani (of record), or Survilo (Survilo, L.I. et al., Vestsi Akademii Navuk Belarusi, Seryya Khimichnykh Navuk, 4: 103-107, 1997; abstract only). The rejection over Stanta is withdrawn. Upon further consideration, this rejection is applied to claim 77. **Therefore, claims 70,71, 77 and 78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Katoh (U.S. Patent 5,591,589; issued 1/7/1997) in view of either Yamamoto (of record), Tarutani (of record), or Survilo (Survilo, L.I. et al., Vestsi Akademii Navuk Belarusi, Seryya Khimichnykh Navuk, 4: 103-107, 1997; abstract only).**

7. Claim 73 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Canfield (WO/87/00289;) in view of Yamamoto (of record). Upon further consideration, this rejection is applied to claim 77. **Therefore, claims 73 and 77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Canfield (WO/87/00289;) in view of Yamamoto (of record).**

8. Claim 75 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Katoh (supra) in view of Canfield (WO/87/00289;) and further in view of Yamamoto (supra) for the reasons of record. Upon further consideration, this rejection is applied to claim 72 and to claim 77. **Therefore, claims 72, 75 and 77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Katoh (supra) in view of Canfield (WO87/00289) and further in view of Yamamota (supra).**

Response to Arguments:

9. Applicants' arguments have been carefully considered but fail to persuade. Applicant states that the prior art of record neither discloses nor suggests a methods which takes a sample and measures conjugated Tg, non-conjugated Tg and total Tg and compares the ratio of either conjugated or non-conjugated Tg to total Tg with the same ratio determined from samples taken from normal subjects and subjects have benign disease and determines malignancy of a thyroid tumor based on comparison of the ratios. To support this statement applicants point to the fact that none of Nakamura, Satomura and Katoh teach a realationship between different Tg lectin-reactivity with malignancy of a thyroid tumor. Applicants then go on to state that Yamamoto fails to compare lectin reactivity between malignant thyroids and benign thyroids (as recited in

the claims) but instead makes a comparison between malignant and normal thyroids. This is not found persuasive, because as pointed out in earlier Office actions, Yamamoto clearly compares malignant thyroids to benign and to normal on at least on pages 138 and pages 142. Yamamoto teaches that thyroglobulin isolated from malignant thyroid tumor tissue has a different DEAE-cellulose ion exchange elution pattern from thyroglobulin isolated from benign and from normal thyroids (page 138, first –2nd col.). Yamamoto teaches that the carbohydrate chains of thyroglobulin derived from the benign tumor had the same structures as those thyroglobulin derived from normal thyroid. Yamamoto teaches that thyroglobulin derived from malignant thyroid tumor contains less sialic acid, contains less high-mannose type carbohydrate moieties, contains oligosaccharides of high molecular mass with repeating Gal-GlcNAc disaccharides and peripheral alpha-fucosyl residues than does thyroglobulin isolated from normal and benign thyroid tissue (page 142, 2nd col – page 143, 1st col). Yamamoto also teaches that using the lectin, ConA, one can differentiate between thyroglobulin isolated from malignant thyroid from thyroglobulin isolated from normal and benign thyroid. ConA affinity chromatography demonstrates that thyroglobulin from malignant thyroids contains more triantenary complex-type oligosaccharides than thyroglobulin from normal thyroids; RCA affinity chromatography demonstrates that thyroglobulin from malignant thyroids has a greater amount of asialo complex-type carbohydrate chains than does thyroglobulin from normal thyroids.

Applicants then argue that the data provided by Tarutani does not support a conclusion that malignant is distinguished from benign based on lectin reactivity of thyroglogublin because the data for malignant and benign appears to overlap. If such a standard were applied to applicants' data, then the same conclusion could be reached for Figures 1-3, where there appears

to be overlap of the ratios. As stated in the previous Office action, Tarutani teaches that the percent of total thyroglobulin that binds to Con-A is different for trabecular carcinoma compared to either follicular adenoma (a benign condition) or normal thyroid tissue (see page 855, Table II). Therefore, Tarutani supplies the teaching that lectin reactivity is different for a malignant condition compared to a normal or a benign condition.

Applicants then argue that the claims are not obvious over the teachings of Survilo, because Survilo fails to disclose a comparison between normal and goiterous thyroids. This is not found persuasive because the claimed methods do not require such a comparison, only a comparison between malignant and benign and malignant and normal, which comparison is made by Survilo.

Applicants go on to argue that none of the references or the combination of references suggest to one of ordinary skill in the art to make a double comparison (malignant to both normal and benign disease). This is not found persuasive because all of the cited references include a comparison of lectin reactivity for thyroglobulin isolated from malignant to lectin reactivity for thyroglobuin isolated from benign and from normal.

Applicants further argue that the suggestion of the method of claim 73 is not found in the references (Canfield or Yamamoto). This is not found persuasive because as stated in the previous rejection, Yamamoto teaches that thyroglobulin derived from malignant thyroid tumor contains less sialic acid than does the thyroglobulin of normal or benign thyroids, and that RCA-affinity chromatography demonstrates that thyroglobulin from malignant thyroids has a greater amount of asialo complex-type carbohydrate chains than does thyroglobulin from normal thyroids. Therefore, Canfield's teaching of a method to measure differentially glycosylated

thyroglobulin and Yamamoto's teaching that thyroglobulin derived from malignant thyroid tumor contains less sialic acid than does the thyroglobulin of normal or benign thyroids clearly suggests the claimed method, because Yamamoto teachings provide the nexus between differential glycosylation and malignancy of thyroids. Thus, the purpose of the claimed methods is suggested by the prior art.

Double Patenting

10. Claims 59, 68, 69, and 74 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, and 5-9 of U.S. Patent No. 5,780,247 in view of either Yamamoto (of record), Tarutani (of record) or Survilo (Survilo, L.I. et al., Vestsi Akademii Navuk Belarusi, Seryya Khimichnykh Navuk, 4: 103-107, 1997; abstract only). The claimed inventions are an obvious species of method that are within the scope of claims 1 and 5-9 of U.S. Patent No. 5,780,247. In view of the teachings of either Yamamoto, Tarutani or Survilo, that thyroglobulin is a glycosylated protein and that thyroglobulin derived from malignant thyroids contains a different glycosylation pattern, and in view of the teachings that this can be observed by measuring differences in lectin-reactivity, the claimed inventions are an obvious species of the methods of claims 1 and 5-9 or U.S. Patent 5,780,247.

Applicants' remarks concerning the filing of terminal disclaimer when allowable subject matter is determined is acknowledged.

11. Claims 70, 71 and 78 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 3 of U.S. Patent No. 5,591,589 in view of either Yamamoto (of record), Tarutani (of record) or Survilo (Survilo, L.I. et al., Vestsi Akademii Navuk Belarusi, Seryya Khimichnykh Navuk, 4: 103-107, 1997; abstract only). The claimed inventions are an obvious species of method that are within the scope of claims 1 and 3 of U.S. Patent No. 5,591,589. In view of the teachings of either Yamamoto, Tarutani or Survilo, that thyroglobulin is a glycosylated protein and that thyroglobulin derived from malignant thyroids contains a different glycosylation pattern, and in view of the teachings that this can be observed by measuring differences in lectin-reactivity, the claimed inventions are an obvious species of the methods of claims 1 and 3 or U.S. Patent 5,591,589.

Applicants' remarks concerning the filing of terminal disclaimer when allowable subject matter is determined is acknowledged.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne Holleran, whose telephone number is (571) 272-0833. The examiner can normally be reached on Monday through Friday from 9:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached on (571) 272-0832. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Official Fax number for Group 1600 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Anne L. Holleran
Patent Examiner
March 23, 2006

LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER